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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JUL 1 1992

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

**MEMORANDUM:** 

SUBJECT: Chlorpropham; product chemistry.

[CBRS No: 9482; MRIDs: 421837-01,02,03:

DP Barcode: D174276]

FROM:

Dennis McNeilly, Chemist

Special Review Section II

Chemistry Branch II - Reregistration Support

Health Effects Division [H7509C]

THRU:

Francis B. Suhre, Section Head

Special Review Section II

Chemistry Branch II - Reregistration Support

Health Effects Division [H7509C]

TO:

Venus Eagle, PMT 71 Reregistration Branch

Special Review and Reregistration Division [H7508C]

and

Robert Taylor, PM 25

Fungicide-Herbicide Branch

Registration Division [H7505C]

Attached please find a review of product chemistry data submitted by Aceto Agricultural Chemicals Corp. in response to the C Chlorpropham Registration Standard Update (10/16/91). This data was reviewed by Dynamac Corp. under the supervision of CBRS, HED.

This information has undergone secondary review in CBRS and is consistent with Chemistry Branch policies.

Please see the conclusions in the attachment regarding the acceptability of the data submitted by the registrant.

If you need additional input please advise.

Attachment 1: Review of Chlorpropham Product Chemistry Data.

CC (with attachment): D. McNeilly; SF: Update File; Dynamac; Circulation. RDI: SH, 06/29/92; MM, 6/30/92; EZ, 06/30/92. H7509C: DMM; dmm; CM-2; Rm 800D; X305-5934; 06/22/92

7-1-02 heres - 6-5-12

# PRODUCT CHEMISTRY DATA SUMMARY Aceto 98% T (EPA Reg. No. 2749-102)

Guideline Number	Requirement	Requirement Fulfilled?	MRID Number
61-1	Product Identity and Disclosure of Ingredients	P	42183703 CSF 4/7/88
61-2	Beginning Materials and Manufacturing Process P		42183703
61-3	Discussion of Formation of Impurities P		42183703
	Proliminary Analysis P		42183702
→ 62-2	Certification of Ingredient Limits P		42183703 CSF 4/7/88
62-3	Analytical Methods to Verify the Certified	N	
	Limits	10	42183701
63-2	Color	P	42183701
63-3	Physical State	P	42183701
63-4	Odor	r P	42183701
63-5	Melting Point	<del>-</del>	42103/01
63-6	Boiling Point	N/A	45165561
63-7	Density, Bulk Density or Specific Gravity	P	42183701
63-8	Solubility	P	42183701
63-9	Vapor Pressure	<u>.P</u>	42183701
63-10	Dissociation Constant	P	42183701
63-11	Octanol/Water Partition Coefficient	P	42183701
63-12	pH	P	42183701
63-13	Stability	· P ·-	42183701
63-14	Oxidizing or Reducing Action	N	
63-15	Flammability	N/A	
63-16	Explodability	N	
63-17	· ·	N	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	N	



Final Report

CHLORPROPHAM Shaughnessy No. 018301 (CBRS No. 9482; DP Barcode D174276; Case 0271)

# TASK 4 Registrant's Response to Product Chemistry Data Requirements

June 10, 1992

Contract No. 68-D2-0053

Submitted to: U.S. Environmental Protection Agency Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
22.75 Research Boulevard
Rockville, MD 20850-3268

#### **CHLORPROPHAM**

## Shaughnessy No. 018301

# (CBRS No. 9482; DP Barcode D174276; Case 0271)

# Task 4

## REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

#### BACKGROUND

In response to the Chlorpropham Reregistration Standard Update dated 10/16/91, Aceto Agricultural Chemicals Corporation has submitted three volumes of product chemistry data (CBRS No. 9482; 1992; MRIDs 42183701-42183703) for the 98% technical (T; EPA Reg. No. 2749-102). The submitted data and our conclusions are discussed below.

# 61-1. Product Identity and Disclosure of Ingredients

The Chlorpropham Reregistration Standard Update dated 10/16/91 requires updated information pertaining to the product identity of the Aceto 98% T (EPA Reg. No. 2749-102). In response, Aceto has submitted information (1992; MRID 42183703) and a Confidential Statement of Formula (CSF) dated 4/7/88, which is presented in the Confidential Appendix. These data do not satisfy the requirements of 40 CFR \$158.155 (Guideline Reference No. 61-1) regarding product identity for the Aceto 98% T (EPA Reg. No. 2749-102) because an impurity, which is listed with a 0.20% maximum on the statement of identity (MRID 42183703), is not included on the CSF. We note that the nominal concentration of the active ingredient does not reflect the preliminary analysis and is the same as the proposed lower certified limit. The nominal concentrations of the impurities are the same as the upper certified limits. Nominal concentrations of both the active ingredient and impurities must be established to reflect the preliminary analysis as described in Subdivision O of the Pesticide Assessment Guidelines. In addition, the registrant has been required to submit additional preliminary analysis data including analysis for an impurity, and an explanation regarding the correlation between a second impurity and a set of impurities identified in the preliminary analysis. Should the requested preliminary analysis data reveal additional impurities at ≥0.1% or of toxicological significance, then nominal concentrations will be required for these impurities as well. Additional data are required.

# 61-2. Description of Starting Materials and Manufacturing Process

The Chlorpropham Reregistration Standard Update dated 10/16/91 requires updated information pertaining to the starting materials and the manufacturing process of the Aceto 98% T (EPA Reg. No. 2749-102). In response, Aceto has submitted (1992; MRID 42183703) information concerning the suppliers and specifications of the starting materials along with a description of the manufacturing process for the 98% T, which is presented in the Confidential Appendix. These data do not satisfy the requirements of 40 CFR \$158.160 and \$158.162 (Guideline Reference No. 61-2) regarding the starting materials and the production process for the Aceto 98% T (EPA Reg. No. 2749-102) because the registrant did not provide the following: (i) the duration of the process; (ii) the relative amounts of the materials used; (iii) a description of the equipment used; (iv) a description of any purification procedures (including procedures to recover or recycle starting materials or the substance produced); and (v) quality control measures used to ensure the purity of the product. Additional data are required.

# 61-3. Discussion of Formation of Impurities

The Chlorpropham Reregistration Standard Update dated 10/16/91 requires an updated discussion of the formation of impurities in the Aceto 98% T (EPA Reg. No. 2749-102). In response, Aceto has submitted (1992; MRID 42183703) a discussion of impurities formed during the production of the 98% T, which is presented in the Confidential Appendix. This information does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the Aceto 98% T (EPA Reg. No. 2749-102) because the registrant must clarify the identity and source of one impurity (see page 8). In addition, discussion of the following potential sources of impurities is required: (i) the degradation of the ingredients in the product after production but prior to use; (ii) post-production reactions between ingredients in the product; (iii) migration of components of the packaging materials into the product; and (iv) carryover of contaminants from use of the production equipment for other products. Additional information is required.

#### 62-1. Preliminary Analysis

The Chlorpropham Reregistration Standard Update dated 10/16/91 requires updated information pertaining to preliminary analysis of the Aceto 98% T (EPA Reg. No. 2749-102). In response, Aceto has provided (1992; MRID 42183702) preliminary analysis data for eight batches of the 98% T. These data are presented in the Confidential Appendix. These data do not satisfy the

requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis of the Aceto 98% T (EPA Reg. No. 2749-102) because samples were not analyzed for one impurity for which a 0.20% maximum was identified in product composition (reference MRID 42183703), and which the discussion of formation of impurities indicated to be present at  $\geq 0.1\%$ . In addition, a set of impurities must be further identified, or the registrant must provide a complete explanation as to why this component is presented as a single impurity on the CSF. Additional data are required.

#### 62-2. Certification of Limits

The Chlorpropham Reregistration Standard Update dated 10/16/91 requires updated information pertaining to the certified limits of the Aceto 98% T (EPA Reg. No. 2749-102). In response, Aceto has submitted a CSF dated 4/7/88 and a list of impurities with maximum levels (1992; MRID 42183703) for the 98% T. presented in the Confidential Appendix. These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits for the Aceto 98% T (EPA Reg. No. 2749-102) because an upper certified limit is required for an impurity, which is listed with a 0.20% maximum on the statement of identity (MRID 42183703), but is not presented on the CSF. We note that the certified limits listed on the CSF for the active ingredient do not reflect the preliminary analysis and differ from the statement of identity (MRID 42183703). Nominal concentrations of both the active ingredient and impurities must be established to reflect the preliminary analysis as described in Subdivision O of the Pesticide Assessment In addition, the registrant has been required to Guidelines. submit additional preliminary analysis data including analysis for an impurity, and an explanation regarding the correlation between an additional impurity and a set of impurities identified in the preliminary analysis. Should the requested preliminary analysis data reveal additional impurities at ≥0.1% or of toxicological significance, then upper certified limits will be required for these impurities as well. The registrant must submit a revised CSF on EPA Form 8570-4 (Rev. 12-90). Additional data are required.

#### PHYSICAL AND CHEMICAL CHARACTERISTICS

The Chlorpropham Reregistration Standard Update dated 10/16/91 requires updated information pertaining to the physicochemical properties of chlorpropham. In response, physical and chemical characteristics for the 98% T (EPA Reg. Nos. 2749-102) have been submitted by Aceto (1992; MRID 42183701). These properties are presented in Table 1. The submitted data do not satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-2

through 63-5, and 63-7 through 63-13) for the submitted characteristics because the registrant did not specify the substrate (for all determinations except melting point) or the methods used. The following information is also required: (i) for density and pH, the temperature at which determinations were made; (ii) solubility of the 98% T in nonpolar solvents; (iii) for dissociation constant and octanol/water partition coefficient, the reason the data requirements for these characteristics are not applicable to the 98% T; and (iv) stability of the 98% T on exposure to sunlight and to metals and metal ions. In addition, data requirements remain outstanding for the following physical/chemical characteristics of the 98% T: oxidizing or reducing action, explodability, storage stability, and corrosion characteristics (Guideline Reference Nos. 63-14, -16, -17, and -20).

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Table 1. Physical and chemical properties of the 98% T (EPA Reg. Nos. 2749-102). Data are from MRID 42183701.

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description (Substrate)		
63-2.	Color	white or grey to brown fused solid		
63-3.	Physical state	solid		
63-4.	Odor	faint characteristic organic odor		
63-5.	Melting point	35 C (TGAI)		
63-6.	Boiling point	257 C		
63-7.	Density, bulk density, or specific gravity	1.2 g/mL		
63-8.	Solubility	89 mg/L water (25 C) 400 g/100 mL methanol at 20 C		
63-9.	Vapor pressure	<10 <sup>-6</sup> at 20 C		
63-10.	Dissociation constant	n/a		
63-11.	Octanol/water partition coefficient	n/a •		
63-12.	рН	7 + 0.5		
63-13.	Stability	stable below 100 C slowly hydrolyzed under acidic or alkaline conditions.		

### MASTER RECORD IDENTIFICATION NUMBERS

#### References (used):

42183701 Wise, J. (1992) Chlorpropham Physical and Chemical Properties. Unpublished study prepared by Aceto Agricultural Chemicals Corp. 18 p.

42183702 Wise, J. (1992) Chlorpropham Preliminary Analysis. Unpublished study prepared by Aceto Agricultural Chemicals Corp. 22 p.

42183703 Wise, J. (1992) Chlorpropham Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Aceto Agricultural Chemicals Corp. 27 p.